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SUN SCIENTIFIC LLC

MAY 16 2007

510 (k) Summary

Date Prepared [21 CFR 807.92(a)(1)]

5/11/07

Submitter's Information [21 CFR 807.92(a)(1)]

This 510(k) is being submitted by Joseph Azary (consultant) on behalf of Sun Scientific LLC Joseph Azary can be contacted by telephone at (203) 944-9320 or fax at (203) 944-9317.

Regulatory Consultant

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Manufacturer / Sponsor

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FDA Establishment Registration is pending.

NOTE: Please have the FDA Substantial Equivalence letter reflect this device is a product of Sun Scientific LLC

Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Device Trade Name: Leg Compressor & PFAB, Leg Compressor & Pre-Filled Air Bladder
Device Common, Usual, or Classification Names: Compression Bandage, Compression Legging, Bandage

Classification: ~~Unclassified, Product Code FRO~~ MHW, Class I

Predicate Device [21 CFR 807.92(a)(3)]

The subject device is most similar to the following types of devices:
Unna Boot Dressing by Graham Field - K883224
Unna Sleeve by ACI Medical - K903532
Unna Flex Elastic Unna Boot by Convatec – Exempt from 510(k), classified as "FQM"
Hydrasorb Sterile Dressing by Avitar - K973260
C-Boot - K041659

Description of the Device [21 CFR 807.92(a)(4)]

The device includes a Leg Compressor and a Pre-Filled Air Bladder (PFAB).

The PFAB does not apply pressure, but when it is used in conjunction with a compression bandage, it will exert local pressure (because of the air pocket). Compression bandages exert pressure, therefore the pre-filled air bladder will redistribute the pressure that the bandage would already by supplying.

Overall the device is meant to redistribute and apply pressure to the venous ulcer. It has been found over the years that compression bandages or stockings healed more venous leg ulcers than no compression.[1]

[1] Nelson, E, Cullum, N, and Jones, J, *"Venous Leg Ulcers"* published in American Family Physician, April 2005.

If the venous ulcer is kept covered and clean with applied pressure the healing process is more effective. The concept behind this device is to keep the wound covered and apply pressure on the wound.

PFAB (Pre-Filled Air Bladder)

The PFAB is an oval shaped polyurethane pre-filled air bladder with four flanges. The tips of the flanges have medical adhesive, which adheres to the skin. The bottom of the PFAB has medical grade hydrophilic foam, which will cover the ulcer and is used to absorb the exudates.

The PFAB will be offered in three sizes (Small, Medium, and Large). The dimensions are as follows:

Size	Dimensions (Length x Width)	Flanges	Tape (thickness)
Small	2" x 1.5"	1.5"	0.75"
Medium	4.5" x 2.5"	1.5"	0.75"
Large	6" x 4"	1.5"	0.75"

Leg Compressor

The leg compressor is used to hold the PBAB in place and apply additional pressure. The leg compressor contains an air chamber that is made of 2 layers of urethane film. The outer black fabric is Nylon. The leg compressor also has a self adjusting manometer attached to the outside to measure the pressure within the air bladder, which will be situated along the Great Saphenous Vein.

The manometer is used for reference only and is not meant to be used for accurate measurements of pressure.

The Leg Compressor includes a safety release valve to deflate the compressor. In addition, the manometer is color coded. As a precaution the user should not inflate the compressor in the red zone.

The pressure at the beginning of the red zone is approximately 30 mm Hg, which is similar to the pressure from a typical Umma Boot or compression bandage.

Intended Use [21 CFR 807.92(a)(5)]

To assist in the management of venous stasis ulcers by applying pressure.

Technological Characteristics [21 CFR 807.92(a)(6)]

Sun Scientific LLC believes that the subject device is substantially equivalent to the predicate devices.

Performance Data [21 CFR 807.92(b)(1)]

The materials that make contact with the patient are biocompatible and are identical to the materials used in one of the predicate devices.

Conclusion [21 CFR 807.92(b)(3)]

We believe the changes are minor and conclude that the subject devices are as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Sun Scientific, LLC
% Azary Technologies, LLC
Mr. Joseph M. Azary
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Shelton, Connecticut 06484

MAY 16 2007

Re: K070457
Trade/Device Name: Sun Scientific LLC – Leg Compressor and PFAB
Regulation Number: 21 CFR 880.5075
Regulation Name: Elastic bandage
Regulatory Class: I
Product Code: MHW
Dated: February 12, 2007
Received: February 20, 2007

Dear Mr. Azary:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K070457**

Device Name: Sun Scientific LLC – Leg Compressor and PFAB

Indications For Use:

To assist in the management of venous stasis ulcers by applying pressure.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K070457